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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,711	07/27/2001	Carlota Vinals y de Bassols	BM45324	7936

25308 7590 10/22/2002

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,711

Applicant(s)

Y DE BASSOLS, CARLOTA
VINALS

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election

1. Applicant's response to restriction filed on 7/23/02 is acknowledged. Claims 27-60 have been canceled. New claims 61-68 have been added. Applicant's election without traverse Group 1 claims 27-38, 53-54 drawn to polypeptide is acknowledged. Claims 27-38, 53-54 have been cancelled and replaced with new claims 61-68 drawn to polypeptide. Claims 61-68 are under examination.

Priority

2. This application is a 371 of PCT/EP99/03822 filed on 5/31/1999. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy Application No. Great Britain 9811945.6 filed on 6/3/1998 has been placed in the application. The examiner has reviewed the priority documents and found that SEQ.ID.NO 2 containing 813 amino acid polypeptide has not been disclosed in the application Great Britain 9811945.6 and therefore, claims 61-68 with respect to SEQ.ID.NO: 2 are granted priority as of 5/31/1999. Claims 61-68 with respect to SEQ.ID.NO: 4 also get priority as of the filing date 5/31/1999 of the application PCT/EP99/03822 since SEQ.ID.NO: 4 is first disclosed in this application.

Information Disclosure Statement

3. No Information Disclosure Statement has been filed with this application.

Specification - Informalities

4. It is noted that Abstract of the Disclosure is missing. If applicant desires to include the abstract from PCT/EP99/03822, the Office would consider and a copy of the abstract will be inserted in to the specification.

There is no brief description of the drawing as set forth in 37 C.F.R.1.74

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Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 61-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 is rejected as being vague and indefinite for the recitation of "matching." As written it is impossible to understand whether applicant is claiming an isolated polypeptide comprising an amino acid sequence matching full length SEQ.ID.NO: 2 or 4 or something else.

Claim 68 recites the limitation " vaccine" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 61 is rejected as being vague and not clear in reciting " T-cell immune response to a polypeptide having the sequence of SEQ.ID.NO: 2 or SEQ.ID.NO: 4" It is not clear what T-cell immune response applicant intend to mean. Does applicant intend to mean T-cell mediated immune response, which induces TH1 or TH-2 cytokine dependent immune response or something else?

Claim Rejections - 35 USC 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 61-64 and 67-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartos et al 1988(J.Infec.Dis, 158; 761-765).

Claims are directed to an isolated polypeptide comprising (a) an amino acid sequence matching SEQ.ID.NO: 2 or 4 (b) an immunogenic polypeptide comprising a fragment of SEQ.ID.NO: 2 or 4 where in the polypeptide, when administered with a carrier induces an antibody response.

Bartos et al disclose an isolated polypeptide, outer membrane protein i.e., OMP from whole cell lysate of 50 strains of *M.catarrhalis* (page 762, left and figure 1). Polyclonal antibodies were produced by administering (i.e., immunizing) p-antigen to rabbits (page 764, right column first paragraph) indicating surface antigens are immunogenic. Applicant's use of the open-ended term "comprising" in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on the disclosed isolated polypeptide, OMP from *M.catarrhalis*. Whole cell lysates from *M.catarrhalis* inherently comprise the amino acid sequence as set forth in the SEQ.ID.NO: 2 or 4 and fragments of SEQ.ID.NO: 2 or 4 See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art protein and the claimed isolated polypeptide comprising (a) an amino acid sequence matching SEQ.ID.NO: 2 are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated polypeptide comprising SEQ.ID.NO: 2 with the polypeptide of prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product

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and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

8. Claims 61, 63, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Blattner et al 1997 (Accession number A 64742).

Claims are directed to an isolated polypeptide comprising a member selected from the group consisting of an (a) an amino acid sequence matching SEQ.ID.NO: 2 (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2, where in the isolated polypeptide induces an antibody or T-cell immune response.

Since "matching" in claim 1 is not clear, the office is interpreting the claim as an isolated polypeptide that matches with SEQ.ID.NO: 2 in any place that can elicit an immune response.

Blattner et al disclose an isolated polypeptide (see sequence alignment marked) comprising an amino acid sequence matching SEQ.ID.NO: 2. The art teaches that the antigen or epitope is roughly 5 amino acids in size (Levinson et al Medical Microbiology & Immunology 1994, page 293) can elicit an immune response and react with an antibody. Therefore, Blattner et al meet the limitations (i.e., an isolated polypeptide comprising an amino acid sequence matching SEQ.ID.NO: 2) of the claims.

Status of Claims

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

10/10/02



MARK NAVARRO
PRIMARY EXAMINER